Attorney Docket No. 47563.0004

REMARKS

This responds to the Office Action dated 25 June 2008, and follows the in-person

interview between Examiner Eric Blatt and Applicants' representative L. Grant Foster

on 15 July 2008. Claims 1, 3, 6, 12, 13, 16, 20, 23, 24 and 28 have been amended. No

claims have been canceled. Claims 31-37 were previously withdrawn. Therefore,

claims 1-30 remain pending in the application.

I. Substance of Interview

On 15 July 2008, Applicants' representative L. Grant Foster and Examiner Eric

Blatt engaged in an in-person interview at the U.S. Patent and Trademark Office

(USPTO). Independent claims 1, 12, 20, and 28 were discussed in detail, along with the

disclosure of the instant application. In addition, prior art was discussed, including

U.S. Patent Nos. 6,896,692 to Ginn and 6,535,764 to Imran, as noted in the Interview

Summary.

Various distinctions between the claims pending in the application and the prior

art were discussed. In addition, it was agreed that various amendments, specifically

those set forth in the above-amended claims, may distinguish the claimed invention

over the art of record.

II. Objection to Claims 6 and 13

In the Office Action, the Examiner objected to claims 6 and 13 as allegedly

including informalities. Claims 6 and 13 have been amended to correct such

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informalities. Applicants respectfully request that the objection of claims 6 and 13 be withdrawn.

III. Rejection of Claims 1-30 under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-30 under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,898,692 to Ginn et al. (hereinafter, "Ginn") in view of U.S. Patent No. 6,535,764 to Imran (hereinafter, "Imran"). Applicants respectfully traverse this rejection.

The factual inquiries that are relevant in the determination of obviousness are determining the scope and contents of the prior art, ascertaining the differences between the prior art and the claims in issue, resolving the level of ordinary skill in the art, and evaluating evidence of secondary consideration. (KSR Int'l Co. v. Teleflex Inc., 550 U.S. __, 2007 U.S. LEXIS 4745, at **4-5 (2007) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966))). To establish a prima facic case of obviousness, the prior art references "must teach or suggest all the claim limitations." (M.P.E.P. § 2142.) Moreover, the analysis in support of an obviousness rejection "should be made explicit." (KSR, 2007 U.S. LEXIS 4745, at **37.) "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (Id. (citing In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006))).

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Applicants respectfully submit that the claims at issue are patentably distinct from the cited references. The cited references do not teach or suggest all of the subject matter of these claims.

In accordance with the in-person interview with the Examiner on 15 July 2008, claim 1 has been amended to recite, *inter alia*, "the locking apparatus comprises a ratchet mechanism configured to apply a pressure to the sealing plug to form a seal between the tissue wall puncture and the sealing plug, wherein the first amount of pressure is insufficient to push the sealing plug through a portion of the internal tissue wall puncture." Support for this amendment may be found in Applicants' specification, for example, pages 10 and 12. Ginn, alone or in combination with Imran, does not disclose, teach, or suggest this subject matter.

Instead, Ginn states:

In addition, or alternatively, the plug member 12 may include flanges or other locking elements (not shown) that may slidably engage the guide wire element 116 as the plug member 12 is advanced over the guide wire clement 116. If the plug member is directed proximally, the locking elements may engage the guide wire element 116 and prevent relative movement of the plug member 12 and guide wire element 116. Optionally, the guide wire element 116 may include ratchet elements (not shown) that may allow the locking elements to [sic] over the ratchet elements in a distal direction, but interlock to prevent movement in a proximal direction.

Ginn, col. 19, lines 24-35.

The use of locking elements to engage the guide wire element and advance a plug member does not suggest that such locking elements are configured to "apply a pressure . . . wherein the pressure is insufficient to push the sealing plug through a portion of the internal tissue wall puncture" as required by the claims in the instant

application. Ginn states that "the collet 60 is compressed to substantially seal the lumen 24." (<u>Id.</u>, col. 19, lines 16-17.) However, Ginn does not suggest that the pressure used to compress the collet is limited so that the pressure "is insufficient to push the sealing plug through a portion of the internal tissue wall puncture."

Ginn states that "the plug member 12 and/or handle device 14 may include a bleed back lumen (not shown) for identifying when the plug member 12 has entered the vessel 90." (Id., col. 19, lines 4-6.) Here, Ginn clearly suggests that the plug member enters at least a portion of the "internal tissue wall puncture" because a bleed back lumen is used to identify "when the plug member . . . has entered the vessel." If the plug member of Ginn enters the vessel, the plug member has penetrated at least a portion of the "internal tissue wall puncture." Thus, Ginn does not disclose, teach, or suggest that locking elements are configured to "apply a first amount of pressure . . . wherein the first amount of pressure is insufficient to push the sealing plug through a portion of the internal tissue wall puncture" as required by the claims in the instant application.

Imran does not overcome the deficiencies of Ginn. The Examiner points to Imran to support the assertion that Imran "show[s] a related closure apparatus comprising a ratchet locking mechanism." (Office Action, page 4.) The Examiner does not point to, and Applicants cannot find, any teaching or suggestion by Imran that the ratchet locking mechanism is configured to "apply a first amount of pressure . . . wherein the first amount of pressure is insufficient to push the sealing plug through a portion of the internal tissue wall puncture" as required by the claims in the instant application.

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In view of the foregoing, Applicants submit that claim 1 is patentably distinct

from the cited references. Accordingly, Applicants respectfully request that the

rejection of claim 1 be withdrawn.

Claims 2-11 depend either directly or indirectly from claim 1. As such,

Applicants respectfully request that the rejection of claims 2-11 be withdrawn.

Claims 12 and 28 have been amended with subject matter similar to the subject

matter amended to claims 1, as discussed above. Claim 20 has been amended to recite,

inter alia, "wherein the one-way lock comprises a ratchet mechanism configured to

allow the sealing plug to be pressured and to seal the puncture without allowing the

sealing plug to be forced into an interior region of the vessel." For the same reasons

articulated with respect to claim 1, claim 20 should be allowable. Accordingly,

Applicants submit that claims 12, 20, and 28 are patentably distinct from the cited

references for at least the same reasons as those presented above in relation to claim 1.

Applicants respectfully request that the rejection of claims 12, 20, and 28 be withdrawn.

Claims 13-19, 21-27, and 29-30 depend either directly or indirectly from claims

12, 20, and 28, respectively. As such, Applicants respectfully request that the rejection

of claims 13-19, 21-27, and 29-30 be withdrawn.

CONCLUSION

For at least the foregoing reasons, Applicants believe that each of the presently

pending claims in this application is in immediate condition for allowance.

Accordingly, Applicants respectfully request a favorable action on the merits. If the

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Examiner has any further comments or suggestions, Applicants invite the Examiner to

telephone the undersigned attorney to expedite the handling of this matter,

Applicants expressly disclaim all arguments, representations, and/or amendments

presented or contained in any other patent or patent application, including any patents or patent

applications claimed for priority purposes by the present application or any patents or patent

applications that claim priority to this patent application. Moreover, all arguments,

representations, and/or amendments presented or contained in the present patent application are

only applicable to the present patent application and should not be considered when evaluating

any other patent or patent application.

Respectfully submitted,

Date: 15 SEVIEMBER 2008

Grant/Foster

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